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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BERCH, MARK L	
ART UNIT	**PAPER NUMBER**
1624	13

DATE MAILED: 01/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/944,096	DANG ET AL.	
	Examiner	Art Unit	
	Mark L. Berch	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,34-39,41 and 42* is/are pending in the application.

4a) Of the above claim(s) *38 and 41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,36* is/are rejected.

7)☒ Claim(s) *34,35,37,39 and 42* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by JP 51105093, JP 53044591, or JP 52023094.

In JP 51105093, see the first compound in the first column of page 706. In JP 53044591, see the second species in the second column of page 779. In JP 52023094, see the compound in first column of page 929. These species all anticipate under the reading given in point 3 below.

The traverse is unpersuasive. The drawing that applicants present on page 23 of the remarks is exactly what the examiner intends. J would correspond to the O-CH_2- group. Applicants are reading limitations into the claim which are not present. The claim language is broad, and the examiner reads no limitations into it. The term "group" which is "heterocyclic" means a group --- any group --- which has a heterocycle present. It does not require that each and every atom be part of a heterocycle. Thus for example, monochlorophenyl is a chlorinated aromatic group, even though not every atom is chlorinated. Similarly, benzyl is a cyclic group, even though not every atom in benzyl is in a cycle (the methylene is not). Chloropyridyl is a heterocyclic group, even though not every atom is in a cycle (the Cl is not). In the claims, the P atom, the 8 and the 9 position of the purine are all linked together by a trivalent "group" denoted as X combined with

Y, and the sole requirement of this "group" is that it be a heterocyclic "group". The "group" present, both in the reference and in the page 23 depiction is heterocyclic, and hence the reference anticipates.

Applicants other argument is that "there must be a directly linkage from the P(O) to the C of the purine ring." The claim has no such language. All that the claim requires is that X with Y form a heterocyclic group. The linkage in e.g. the species of JP 51105093 contains three atoms (2 carbons and a sulfur) which are part of a heterocyclic ring, and hence meets the claim language.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36 is indefinite. The scope of claim 36 is unknown. Which diseases are these? Determining who is in need thereof requires knowing which disease is to be treated. Does the person have to actually have a disease? That is, does this claim cover giving the drug to someone who is healthy?

If not, determining whether a given disease responds or does not respond to such inhibition will surely involve undue experimentation. Suppose that a given Inhibitor X when administered to a patient with Disease D does not obtain a response. Does one then conclude that Disease D does not fall within this claim? Keep in mind that:

A. It may be that the next patient will respond. It is quite common for pharmaceuticals to work only with some people, not all. Thus, how many need to be tested?

B. It may be that the wrong dosage or dosage regimen was employed. It is quite common for pharmaceuticals to work at one dosage, but not at another which is significantly higher or lower. Furthermore, the dosage regimen may be vital --- should the drug be given e.g. once a day, or four times in divided dosages? Thus, how many dosages and dosage regimens must be tried before one is certain that this pharmaceutical won't affect Disease D?

C. It may be that X simply isn't potent enough for Disease D, but that another inhibitor Y is potent enough, so that D really does fall within the claim. Thus, how many different inhibitors must be tried before one concludes that D doesn't fall within the claim?

D. Conversely, if D responds to Y but not to X, can one really conclude that D falls within the claim? It may be that the X result is giving the accurate answer, and that the success of Y arises from some other unknown property which Y is capable of. Thus, when mixed results are obtained, how many more pharmaceuticals need be tested?

E. Finally, suppose that X really will work, but only when combined with Z. There are for example, agents in the antiviral and anticancer technology which are not themselves effective, but the disease will respond when the agents are combined with something else.

As a result, determining the true scope of the claim, that is, who is actually "in need thereof" will involve extensive and potentially open-ended research. Without it,

one skilled in the art cannot determine the actual scope of the claim. Hence, the claim is indefinite.

The traverse is unpersuasive. Applicants point to page 6, lines 18-21, which states that the treatment of two categories of diseases is an "aspect of the present invention." Applicants then point to page 61, which gives some examples of diseases, e.g. diabetes, which fall into those two categories. But the claim language of claim 36 is not limited to that aspect, to those two categories. It covers some other undefined additional material. There is not reason to think that this material in the specification is all that the claim covers. There is no way of knowing what is the full scope of what the claim covers. The material in the specification deals with glucose (and its stored form, glycogen) and its balance with insulin. These are not even mentioned in claim 36. Thus: what else is covered? Does this cover treatment of e.g. cancers, neurodegenerative disorders, etc? The problem here is that so little is known about this. While it is true that FBPase has been studied since the 1970s, no diseases are currently being treated by FBPase-1 inhibitors (the examiner notes that CS-917 may become the first such drug), so one cannot really know who is in need thereof because there is no track record to rely on.

Applicants cite *Skuballa* for the notion that a claim is "not rendered indefinite because it recites diverse utilities." Agreed, but the examiner is not saying that applicants cannot have diverse utilities, but rather that one of ordinary skill in the art does not know what the scope of the claim is. Similarly, applicants cite *Cole* for the idea that law does not require that "every compounds within a claim be equally useful for each and every contemplated application" but the examiner is making no such requirement, but rather saying that it is not clear what the full range of the

contemplated applications actually are. Applicants go on to quote the decision as referring to "theorize some combination of circumstances which would render a claimed ... method inoperative" but that again is not the examiner's concern, but rather, what the intended scope actually is.

With regard to dosage, the examiner is not concerned with the dosage per se. The examiner simply notes that in the long and difficult process to determine what disease would be covered, a failure in an experiment does not necessarily mean that the disease is not covered, because of the possibility that the wrong dosage was being used.

Claims 34-35, 37, 39 and 42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 703-308-4718. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708-308-1235.

Mark L. Berch
Primary Examiner
Art Unit 1624

January 2, 2003